UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

February 10, 2011

DPBARCODE:		D367948
MRID:		47810501, 47810502, 47810503, 47810504, 47810505,47810506, 47810507, 47810508, 47810509
SUBJECT:		Terbutryn Technical
REG. NO. OR FILE SYMBOL:		5383-RGI
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [X]	OR	End-use Product []
INGREDIENTS (PC Codes):		080813
CAS Number:		886-50-0
TEST LAB:		Syngenta Crop Protection, Inc.
SUBMITTER:		Troy Chemical Corporation
GUIDELINE:		830 Guidelines
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		2/10/11

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MEMORANDUM

Subject: Review for 5383-RGI

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell-McFarlane PM 34\Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Troy Chemical Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):	%by wt.
2-(tert-butylamino)-4-ethylamino)-6-(methylthio)-s-triazine	96.6%
Inert Ingredients	3.4%
Total	100.0%

BACKGROUND:

The registrant has submitted a product chemistry package in support of a new active ingredient. The package includes a label, Confidential Statements of Formula (CSF dated 7115/2009 for the basic formulation and CSF dated 217/2011 for alternate formulation 1), and MR.IDs 47810501, 47810502, 47810503, 47810504, 47810505, 47810506, 47810507, 47810508, and 47810509. These studies are intended to satisfy the product chemistry requirements. The contractor has conducted a primary review of this submission and Product Science Branch of Antimicrobials Division has conducted a secondary review which supersedes the primary review.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated June 18, 2008) is consistent with the label declaration.

2. All ingredients are cleared for use in pesticidal products.

3. The product identity and composition is acceptable.

4. The description of the starting materials is acceptable.

5. The description of the formulation process is acceptable.

6. The discussion of the formation of impurities is acceptable.

7. The preliminary analysis is acceptable.

8. All certified limits are acceptable.

9. The enforcement analytical method is acceptable. Although the registrant did not address this requirement, the consultant wishes to use the method employed in *MRID* 47810504 for analysis.

10. The color, physical state, and odor are acceptable. Both the pure active ingredient and the product are white solids. The product has a weak sulfide odor and the pure active ingredient is odorless.

11. The melting point is acceptable as the melting point was found to be 377 K.

12. The boiling point is acceptable as the boiling point was found to be 618 K.

13. The density is acceptable as the density was determined to be 1.20 at 20°C.

14. The water solubility is acceptable. This property was found to vary with temperature but not with pH.

15. The vapor pressure is acceptable as the extrapolated vapor pressure was determined to be 1.68 x 10-6 mm Hg at 20 °5.

16. The dissociation constant in water is acceptable as his value was determined to be 4.47 at 23.4 °C.

17. The octanol\water partition coefficient is acceptable as this value is independent of temperature and pH. The log Powwas found to be 3.7 at 20°C.

18. The pH is acceptable as the pH of a 1% solution was determined to be 5.91.

19. The stability is unacceptable. No data was submitted for this requirement. Data for stability is needed to register a technical grade active ingredient/manufacturing use product. This guideline (830.6313) includes stability to normal and elevated temperatures and reaction to metal and metal ions.

20. The oxidation/reduction potential is unacceptable. The study states that/ oxidizing properties are predicted to be negative; however, the study states nothing about reducing potential.

21. The flammability is acceptable as the product is not potentially flammable.

22. The explodability is acceptable as the product is not potentially explosive.

23. The studies for storage stability and corrosion characteristics were not submitted. These data are required for manufacturing-use products/technical grade active ingredients. These data are often conducted jointly under GLP compliance. These data can be submitted as a condition of registration.

24. The viscosity is unacceptable as this requirement was not addressed in the / submission.

25. The miscibility is unacceptable as this requirement was not addressed in the / submission.

26. The dielectric breakdown voltage is unacceptable as this requirement was not / addressed in the submission.

27. The UVNisible Absorption data is acceptable.

28. Under the "Directions for Use" section of the label, change "PBI" to read "polybenzimidazole (PBI)."

29. Under the "Pesticide Storage" section of the label, add instructions that specify what to do if the product leaks or spills from the product container.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSFs for 383-RGI to be acceptable and the data for 5383-RGI to be unacceptable for the reasons discussed in the findings. The registrant must remedy the issues before successful registration may proceed.